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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,006

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Mark Jason Heath Ellison

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,006	Applicant(s) ELLISON ET AL.	
	Examiner MINA HAGHIGHATIAN	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the Amendments and Remarks filed on 12/27/07.

Claims 32, 35, 40-41, 48 and 51 have been amended and claim 55 has been cancelled.

No new claims have been added. Accordingly, claims **28-54** remain pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Hallworth (EP 0750492).

Hallworth teach inhalation composition containing lactose pellets (col. 2, lines 10-16). The final powder composition desirably contains 0.1 to 90% w/w, preferably 1-50% w/w of medicament relative to the weight of the lactose pellets (see [0012]). The final powder composition desirably contains 0.1 to 90% w/w and preferably 50-99% w/w lactose pellets (see [0023]).

Claims 52-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Ganderton et al (5,254,330).

Ganderton et al teach pharmaceutical excipients useful in dry powder inhalers.
The preferred excipients are crystalline sugars such as **lactose**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 28-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ganderton et al (5,254,330) in view of Dahl et al (6,635,278).

Ganderton et al teach pharmaceutical excipients for dry powder inhalers including crystalline lactose sugars. The crystalline lactose is prepared by controlled crystallization from an aqueous medium. The solvents may be water and/or ethanol. The excess liquid is removed prior to drying (see columns 2-3). The said excipients

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comprise at least 80% and preferably at least 95% by weight of the novel carrier materials. The novel excipients may be admixed with any suitable pharmaceutical agents in order to provide a dry powder inhalant composition. Examples of suitable active agents for oral inhalation include steroids, anti-inflammatory agents, bronchodilators, anti-histamines, etc. The particle size of the active agents are in the range of 0.1 to 10 microns (see columns 3-4). The carrier particles have an average particle size of from 5.0 to 1000 microns (col. 2, lines 6-13). Ganderton et al lacks disclosure on process of granulation.

Dahl et al teach compositions comprising adenine and an alkaline excipient and methods of making the said composition. The process includes wet granulation, drying, milling, etc. The intragranular compositions are blended, mixed with a granulating solvent, dried and milled to obtain granules of a desired particle size. The intragranular composition is mixed with excipients. The excipients include an alkaline excipient and one or more additional excipients such as lactose, or lactose monohydrate (col. 4, lines 13-30). The formulations may be made as a powder or granules (col. 5, lines 10-14).

Dahl et al also teach that unit dosage formulations are made by wet granulation or by direct compression. The granulation provides granules of desired size. Wet granulation is accomplished using water or organic liquids such as acetone, or alcohols such as ethanol. Fluid bed drying is preferred over tray drying. The amount of solvent in the wet granulation process is usually about 5-50% of the weight. Lactose is used in an amount of about 50 to 70% of the total diluent. The wet components are milled through

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a #4 mesh screen and drier, and desired material is milled to desired geometric mean particle size.

Although the combined references do not recite the geometric diameters as claimed, they teach granulating and milling the excipients and active particles to the desired size.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Ganderton et al on preparing pharmaceutical carriers for inhalation such as lactose particles with teachings of Dahl et al on specific method of making excipients for inhalation including lactose granules as excipients made by method of wet granulation with a reasonable expectations of successfully preparing suitable and stable carrier/excipients for effective delivery of active agents to the respiratory system. In other words, the claims would have been obvious because the technique for improving a particular process was part of the ordinary capabilities of a person of ordinary skill in the art, in view of the teaching of the technique for improvement in other situations.

Response to Arguments

Applicant's arguments filed 12/27/07 have been fully considered but they are not persuasive.

Applicants arguments with regard to the rejections are not persuasive and all the recited rejections are maintained.

Applicant argues that -Hallworth describes how “the preparation and storage of lactose pellets is desirably carried out under anhydrous conditions to obviate any adverse effects of free moisture” so the granulation in the presence of the instant fluid binding agent and subsequent drying is not disclosed or taught at all-. This is not commensurate with the scope of claims. Claims 52-54 are under anticipatory rejection over Hallworth. These claims do not recite and granulation, drying or fluid bed limitation. In fact the only limitation in claims 52-54 is “lactose granules” which is taught by Hallworth.

Applicants make analogous arguments regarding rejection of claims 52-54 over Ganderton, stating that Ganderton does not recite “the concept of active drying”. Again the limitation of “active drying” is not in the said claims.

Applicant argues that “Dahl et al are silent as to the preparation of crystals or pellets for inhalation therapy, and the Dahl et al. general teachings of wet granulation and fluid bed drying do not provide any general or specific guidance to make the claimed excipient for dry powder inhalation giving a concentration of primary carrier material at stage 2 of the twin stage impinger of at least 5%”. This is not persuasive because 1) Ganderton teaches preparation of powder excipients for inhalation and Dahl teaches preparation of powders and granules of lactose and other excipients by wet granulation and drying them. One of ordinary skill in the art could have tried the same powder/granules for inhalation as taught by Ganderton. 2) The arguments are not commensurate with the scope of claims. Claim 28 is drawn to excipients made of a primary carrier. Bothe Ganderton and Dahl references teach that. The recitation of “for

dry powder inhalation” is considered an intended use and is not given weight. The recitation of “obtained by granulating.....” makes the claim a product-by-process claim, in which the process is not given weight.

No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghighatian/

Mina Haghighatian
Patent Examiner
March 16, 2008